EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO. 2187**
THIS DOCUMENT RELATES TO:	
ALL WAVE 9 CASES IDENTIFIED IN EXHIBIT A[1]	

DEFENDANT C. R. BARD, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT CERTAIN OPINIONS AND TESTIMONY OF BRUCE A. ROSENZWEIG, M.D.

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[1] *See* Exhibit A to Defendant C. R. Bard, Inc.'s Motion to Exclude or Limit Certain Opinions and Testimony of Bruce A. Rosenzweig, M.D.

Defendant C. R. Bard, Inc. ("Bard") hereby submits this Reply Memorandum of Law in Support of its Motion to Exclude or Limit Certain Opinions and Testimony of Bruce A. Rosenzweig, M.D. In support thereof, Bard states as follows:

INTRODUCTION

On August 15, 2019, Bard filed its Motion to Exclude or Limit Certain Opinions and Testimony of Bruce A. Rosenzweig, M.D. [ECF 7412] and accompanying Memorandum of Law [ECF 7413] (collectively, the "Motion"). In Plaintiffs' Response in Opposition to Defendant's Motion to Exclude Bruce Rosenzweig, M.D. for Wave 9 Cases ("Opposition"), attached as Exhibit 1 to their Notice of Adoption [ECF 7450], Plaintiffs chide Bard for its supposed "numerous baseless attacks" on the expert opinions of Dr. Rosenzweig, yet in the next breath concede that three of the six categories of Dr. Rosenzweig's opinions criticized by Bard—his opinions regarding Bard's state of mind or corporate conduct, his narrative descriptions of Bard documents, and his legal opinions—are in fact improper under this Court's prior rulings. Unable to present any valid justification for Dr. Rosenzweig's continued inclusion of such opinions in his Report or testimony,[2] Plaintiffs dismiss the arguments as "form over substance," and state that Dr. Rosenzweig "understands the[] guidelines" previously laid out by the Court regarding "statements to be avoided." Clearly not, or else Dr. Rosenzweig would not have included page after page of such statements concerning state of mind, corporate conduct, narrative, and legal opinions in his Report and testimony. Regardless, Plaintiffs concede such opinions and statements are inadmissible under the Court's prior rulings, and they should also be excluded here.

This leaves three categories of opinions challenged in Bard's Motion still at issue: Dr. Rosenzweig's opinions regarding the alleged insufficiency of Bard's testing, his opinions

[2] Capitalized terms have the same meaning here as in Bard's Motion.

regarding the purported inadequacy of Bard's patient brochures, and his specific causation opinions. With regard to testing, Plaintiffs attempt to recharacterize Dr. Rosenzweig's testing opinions as "clinical trial" opinions, and assert that Dr. Rosenzweig has adequate experience to opine regarding the need for clinical trials. No matter how Plaintiffs seek to frame Dr. Rosenzweig's testing opinions, however, they cannot escape the Court's earlier rulings that Dr. Rosenzweig simply lacks the necessary experience or knowledge to opine regarding the appropriate testing a medical device manufacturer should undertake. Nor can Plaintiffs show any connection between Dr. Rosenzweig's prior experience with clinical trials and his criticisms of Bard's testing. To the contrary, Dr. Rosenzweig's testing opinions are the same sort of unqualified opinions this Court previously ruled inadmissible in Huskey and Edwards. The Court's ruling excluding the similarly unqualified testing opinions of Dr. Brian Raybon in its February 2, 2015 Memorandum Opinion and Order in *Wise v. C.R. Bard*, No. 2:12-cv-01378 (the "*Wise* Opinion"), is similarly instructive, and the same result holds here.

As to patient brochures, Plaintiffs ignore the substance of Bard's challenge and assert only that Dr. Rosenzweig is qualified to opine about marketing materials, including patient brochures, because he deals with this kind of information regularly in his practice. Yet Dr. Rosenzweig's opinions regarding Bard's patient brochures are not grounded in his practice. Rather, he opines on the alleged inadequacy of Bard's patient brochures under the standards of an FDA guidance document for "patient labeling." Nothing in Dr. Rosenzweig's background or credentials indicates that he has the background, qualifications, or experience to opine regarding Bard's compliance with FDA "patient labeling" standards in its marketing materials.

Lastly, with regard to Dr. Rosenzweig's specific causation opinions, Plaintiffs criticize Bard's "strange tack" of supposedly "attacking them generally but providing only limited

examples to make its arguments." To the contrary, Bard's Motion and supporting Memorandum of Law identify and explain in full the challenged specific causation opinions regarding subclinical infection, degradation, contraction, and deformation. Moreover, Plaintiffs' efforts to tie these specific causation opinions to Dr. Rosenzweig's physical examinations or differential diagnoses are ineffective, as Dr. Rosenzweig's own plaintiff-specific reports and deposition testimony disclose that the challenged specific causation opinions were not the result of his examinations or differential diagnoses. Rather, they are grounded in general inferences from literature, his general background, and other *ipse dixit* assertions.

Plaintiffs also argue that Bard violated Pretrial Order 299 ("PTO 299") by filing a separate Motion, instead of merely adopting a prior-filed motion to exclude. Plaintiffs misrepresent this Court's order, as it stated—as to Wave 9 specifically— "[f]or the filing of Daubert motions on general causation issues only, the parties are instructed to file one Daubert motion per expert in the main MDL (MDL 2187) instead of the individual member case." PTO 299 [ECF 6992]. The Court did not prohibit the parties from filing new Daubert motions for general causation experts in Wave 9 entirely. Instead, the Court ordered the parties to file Daubert motions on general causation issues only in the main MDL (MDL 2187), which is what Bard did. Therefore, Bard is in complete compliance with PTO 299 and Plaintiffs' argument fails.

For these reasons, and as supported by the Court's prior rulings, Bard requests that its Motion be granted and the challenged opinions be excluded.

ARGUMENT

I. DR. ROSENZWEIG'S IMPROPER OPINIONS REGARDING BARD'S KNOWLEDGE, STATE OF MIND, OR CORPORATE CONDUCT, HIS NARRATIVE DESCRIPTIONS OF BARD DOCUMENTS, AND HIS LEGAL OPINIONS SHOULD BE EXCLUDED.

Plaintiffs do not and cannot deny that, in accordance with this Court's clear guidance in the *Lewis*, *Huskey*, *Edwards*, and *Tyree* Opinions, Dr. Rosenzweig is prohibited from offering: (i) opinions regarding Bard's knowledge, state of mind, or other matters related to corporate conduct and ethics; (ii) narrative descriptions of Bard documents; and (iii) legal opinions. Though Dr. Rosenzweig's Report and testimony are replete with such improper opinions, Plaintiffs strive to make Dr. Rosenzweig's continuing disregard of the Court's prior rulings an issue for trial, and reproach Bard for even raising the issue at this stage. Plaintiffs fault Bard for purportedly asking the Court "to do precisely what the Court has previously stated it would not do," in light of the Court's prior statements that it would not "repeatedly parse the expert reports and depositions of each expert in relation to this same objection." Plaintiffs suggest any such objections should be addressed at trial.

These assertions entirely miss the point of the Court's prior rulings sustaining defendants' objections to opinions of the type Dr. Rosenzweig yet again attempts to offer here. The Court did not, in the past, defer for trial the question of improper expert testimony relating to knowledge, state of mind, corporate conduct, narrative descriptions, or legal opinions. Rather, it held such opinions inadmissible and excluded them. (*See Lewis* Opinion at 9-10, 35; *Huskey* Opinion at 5-6, 10-12; *Edwards* Opinion at 5-6, 17-18; *Tyree* Opinion at 7-8). The Court's statement that it "will not repeatedly parse the expert reports and depositions of each expert" was an admonition to the parties offering such excluded opinions that they must "tailor expert testimony at trial" in accordance with the Court's prior ruling excluding these opinions. (*See Huskey* Opinion at 5-6;

Edwards Opinion at 5-6; *Tyree* Opinion at 7-8). The comment was not directed against any defendant for offering valid objections to inadmissible expert testimony.

Notwithstanding Plaintiffs' insistence that Dr. Rosenzweig "understands the limitations that the Court has placed on expert testimony—as do Plaintiffs' counsel," there is nothing in the text of Dr. Rosenzweig's Report or testimony to indicate that these lessons have been learned. The innumerable examples of Dr. Rosenzweig's improper opinions in contravention of the Court's prior orders are set forth in Bard's Motion. They will not be repeated here, nor does Bard ask this Court to "parse" each such example. Bard does ask that the Court reaffirm its exclusion of these inadmissible opinions, and again direct Plaintiffs to "tailor expert testimony at trial" in accordance with its rulings. Plaintiffs suggest this is not needed, as the Court "should not assume that Dr. Rosenzweig will use the same words on the witness stand as in his report." The question is then why Dr. Rosenzweig would continue to assert opinions in his report and deposition testimony he knows to be excluded. In light of Dr. Rosenzweig's clear assertion of improper expert opinions in his Report and testimony, there is no need to defer the matter for trial. Clear guidance now will avoid needless controversy later. Each category of admittedly invalid expert testimony should be excluded.

II. DR. ROSENZWEIG CANNOT OFFER OPINIONS REGARDING THE PURPORTED INSUFFICIENCY OF BARD'S TESTING.

Turning to Dr. Rosenzweig's opinions criticizing the adequacy of Bard's testing, Plaintiffs assert that Bard is attempting to "greatly broaden the scope" of the Court's prior orders excluding such testimony from Dr. Rosenzweig, and suggest that Dr. Rosenzweig's testing opinions in this case are admissible because they pertain to "clinical trials," in which Dr. Rosenzweig claims "ample experience," rather than cytotoxicity. These arguments ignore the scope of the Court's

prior rulings, distort Dr. Rosenzweig's opinions, and seek to construct an artificial area of expertise for Dr. Rosenzweig that he does not possess.

The flaw this Court identified in Dr. Rosenzweig's testing opinions in *Huskey* and *Edwards* was not Dr. Rosenzweig's lack of familiarity with ***cytotoxicity***, as Plaintiffs maintain, but rather his lack of familiarity with ***medical device testing***. In *Huskey*, the Court first found that Dr. Rosenzweig was qualified to offer an opinion that Ethicon failed to inform physicians about the risk that its mesh is cytotoxic, because Dr. Rosenzweig "regularly encounters cytotoxicity in his practice, including in women who have polypropylene implants," and stated that he has removed mesh implants as a result of cytotoxicity. (*Huskey* Opinion at 9). Nonetheless, the Court concluded, "I **FIND** that Dr. Rosenzweig is ***not qualified*** to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any experience or knowledge ***on the appropriate testing a medical device manufacturer should undertake***." (*Id*. at 10 (emphasis added)). The Court's ruling in *Edwards* was materially identical. (*Edwards* Opinion at 16-17). Similarly, in the recent *Wise* Opinion, the Court excluded Dr. Raybon's "opinions on Bard's purported failures with respect to the funding and performance of clinical trials on the Avaulta." (*Wise* Opinion at 29). The Court agreed with Bard that, "Dr. Raybon is not qualified to testify about what testing Bard should or should not have conducted prior to placing the Avaulta on the market," as there is "no indication" that Dr. Raybon "has any experience with or knowledge about the appropriate testing a medical device manufacturer should undertake." (*Id*. at 29-30).

In light of these rulings, Plaintiffs' attempt to cure the defects this Court previously found in Dr. Rosenzweig's testing opinions by highlighting his purported "experience with clinical trials—as a physician, as a researcher, and as a teacher," misses the point. The problem in *Huskey* and *Edwards* was not that Dr. Rosenzweig lacked "experience" with cytotoxicity; to the contrary,

the Court expressly found he had adequate experience with cytotoxicity in his practice to testify about it. The problem was that Dr. Rosenzweig lacks experience and knowledge specific to the appropriate testing a medical device manufacturer should undertake, and thus was not qualified to opine that the testing undertaken was insufficient.

Dr. Rosenzweig's testing opinions in this case replicate the same basic error. Indeed, Plaintiffs' efforts to distinguish Dr. Rosenzweig's opinions in this case highlight their similarity to the excluded opinions in *Huskey* and *Edwards*. Plaintiffs state that in this case, Dr. Rosenzweig "is simply saying that some testing to assess particular problems was needed—he is not criticizing testing that was actually done." The same was true in *Huskey* and *Edwards*. In both cases, Dr. Rosenzweig was not "criticizing testing that was actually done" on cytotoxicity; he was criticizing the "fail[ure] to undertake testing 'to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use.'" (*Huskey* Opinion at 9-10; *Edwards* Opinion at 16-17). Likewise, in *Wise*, Dr. Raybon's opinions were directed to Bard's purported "failures" to fund and perform clinical trial. (*Wise* Opinion at 29). This mirrors Dr. Rosenzweig's testing opinion here, criticizing Bard for failing to "conduct[] clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene used in Align to alter inside the woman's body (as well as other complications), and if so, what materials are released into the body as a result, and what impact would those materials have on the body." (Report § III.A.1 at 17; *see also id*. § III.A.2 at 24).[2]

Plaintiffs' efforts to recharacterize Dr. Rosenzweig's opinions in their response as mere "clinical trial" opinions, in order to emphasize his putative experience with clinical trials, is similarly unavailing. Dr. Rosenzweig did not opine on Bard's failure to conduct general "clinical trials"; he specifically criticized Bard's purported failure to undertake "clinically relevant testing"

into particular problems he identified, including mesh alteration and degradation inside a woman's body. As was the case in *Huskey* and *Edwards*, there is nothing to suggest Dr. Rosenzweig has experience and knowledge specific to the appropriate testing a medical device manufacturer should undertake to test for mesh alteration and degradation inside a woman's body. Dr. Rosenzweig's affidavit refers in general terms to his purported experience evaluating clinical trial results in making clinical decisions, participating in clinical trials, reviewing clinical trials for publication, and reviewing clinical trials as a teaching function. (Opposition, Ex. B ¶¶ 4- 7). His *curriculum vitae* lists five clinical trials in which he participated—three drug trials and two contraceptive device trials. (*Id*., Ex. C at 5). Yet nothing in Dr. Rosenzweig's affidavit or his *curriculum vitae* sets forth any experience or knowledge on the "clinically relevant testing" a medical device manufacturer should undertake to test for mesh alteration and degradation inside a woman's body; he simply lacks the relevant expertise to offer an opinion in this area. Likewise, as with Dr. Raybon in *Wise*, there is nothing in Dr. Rosenzweig's affidavit or *curriculum vitae* to indicate he has "training in, knowledge of, or experience with the ***design*** of clinical trials or the ***process*** of testing medical devices." (*Wise* Opinion at 30 (emphasis added)).

Plaintiffs seek to make a virtue of Dr. Rosenzweig's deficit of experience in the field of medical device testing, conceding that he lacks the expertise "to design a specific test," but stating that he can offer "the opinion that Bard needed to conduct clinical testing to better understand these phenomena [the dangers of implantation, the risk of degradation, and the risk of contracture/shrinkage], in order to make its product safer." Given Dr. Rosenzweig's unfamiliarity with "the appropriate testing a medical device manufacturer should undertake," however, such opinions are mere assertions without a qualified basis in Dr. Rosenzweig's knowledge, skill,

experience, training, or education—the essential requirement of expert testimony. Fed. R. Evid. 702(a).

Lastly, Plaintiffs assert that Dr. Rosenzweig is "intimately familiar with the testing Bard has actually done." Plaintiffs' citations do not bear out this assertion. Plaintiffs cite to an excerpt from Dr. Rosenzweig's deposition in which he refers broadly to the alleged need for more long-term testing on the safety of polypropylene mesh products generally. (Rosenzweig Dep. at 213:14-217:5). None of this testimony indicates "intimate familiarity" with Bard's testing, nor does it reflect the necessary qualifications to discuss the appropriate testing a medical device manufacturer should undertake on mesh alteration, degradation, or similar issues. Plaintiffs are simply attempting to construct qualifications that Dr. Rosenzweig does not have.

III. DR. ROSENZWEIG CANNOT OFFER OPINIONS REGARDING THE ALLEGED INADEQUACY OF THE BARD PATIENT BROCHURES.

With regard to Dr. Rosenzweig's opinions challenging the adequacy of Bard's patient brochures, Plaintiffs contend that Dr. Rosenzweig regularly discusses information in patient brochures with his patients, and assert that the expertise needed for Dr. Rosenzweig to opine about the content of patient brochures is similar to the expertise needed to opine about the Instructions for Use ("IFU"), opinions this Court has found Dr. Rosenzweig qualified to give.

Plaintiffs deliberately sidestep the real issue. Dr. Rosenzweig did not offer an opinion regarding whether, from his standpoint as a clinician counseling patients, Bard's patient brochures contain adequate information to guide his discussions. Likewise, he does not confine his criticisms to whether Bard's patient brochures "adequately expressed" the risks associated with its products, which is the opinion Dr. Rosenzweig has offered with respect to the IFU. Instead, Dr. Rosenzweig offers a ***regulatory*** opinion. He cites an FDA guidance document for the proposition that a patient brochure is "considered patient labeling," and interprets the FDA guidance document to mean the

brochure "should include the risks and benefits associated with the device in a manner that is meaningful to the user," which "should be conveyed in an effective and meaningful way to the use [sic] in deciding whether to use a device, or undergo a procedure that uses the device." (Report § III.C.2 at 57). He then purports to evaluate whether Bard's patient brochures meet this standard, and opines that they do not. (*Id*. § III.C.2 at 58). As the Court recently ruled with regard to Dr. Raybon in *Wise*, this exceeds the scope of Dr. Rosenzweig's clinical expertise. (*See Wise* Opinion at 25 (holding that Dr. Raybon "has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law," and limiting his testimony to "the risks he perceives that the Avaulta poses to patients" and whether the IFU conveyed those risks)).

Plaintiffs acknowledge Dr. Rosenzweig's reliance upon the FDA guidance document, but dismiss it as a mere "citation," and argue it is "only logical" that a patient brochure should have information helpful to the patient. Dr. Rosenzweig, however, is not offering an opinion from logic, nor from his knowledge, skill, experience, training, or education. He is offering an opinion regarding Bard's compliance (or non-compliance) with the FDA's guidance regarding patient labeling—an opinion he is admittedly unqualified to give. Allowing Dr. Rosenzweig to offer opinions to the jury premised on his "citation" to an FDA guidance document in which he lacks expertise thus cloaks unqualified regulatory testimony as expert opinion. Dr. Rosenzweig's opinions regarding whether Bard's patient brochures are adequate under FDA standards pertaining to patient labeling should therefore be excluded.

CONCLUSION

For all the foregoing reasons, Bard respectfully requests that the Court exclude or limit certain opinions of Dr. Rosenzweig as set forth above.

Dated: September 13, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2019, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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